



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0493]

Medical Devices; Exemption from Premarket Notification: Powered Patient Transport, All Other Powered Patient Transport

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it has received a petition requesting exemption from the premarket notification requirements for the generic device type, powered patient transport, all other powered patient transport. These devices are motorized devices used to mitigate mobility impairment caused by injury or other disease by moving a person from one location or level to another, such as up and down flights of stairs. This device type does not include motorized three-wheeled vehicles or wheelchairs, and is distinct from the device type, powered patient transport, powered patient stairway chair lifts, which is classified separately within the same regulation. FDA is publishing this notice to obtain comments in accordance with procedures established by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-0493 for “Medical Devices; Exemption from Premarket Notification: Powered Patient Transport, All Other Powered Patient Transport.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Dan Reed, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm.1526, Silver Spring, MD 20993-0002, 240-402-4717.

SUPPLEMENTARY INFORMATION:

I. Regulatory Background

Under section 513 of the FD&C Act (21 U.S.C. 360c), FDA classifies devices into one of three regulatory classes: class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Pursuant to section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and the implementing regulations, part 807 (21 CFR part 807), persons who intend to market a new device are required to submit and obtain clearance of a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is “substantially equivalent” within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

On November 21, 1997, section 206 of the Food and Drug Administration Modernization Act (Pub. L. 105-115) added new section 510(m) to the FD&C Act. On December 13, 2016, section 3054 of the 21st Century Cures Act (Pub. L. 114-255) (Cures Act) amended section 510(m) of the FD&C Act. As amended, section 510(m)(1) of the FD&C Act requires FDA, within 90 days after enactment of the Cures Act and once every 5 years thereafter, to publish in the *Federal Register* a list of each type of class II device that does not require a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness.

As amended by the Cures Act, section 510(m)(2) of the FD&C Act provides that, 1 calendar day after the date of publication of the final list mentioned in section 510(m)(1)(B), FDA may exempt a class II device from the requirement to submit a report under section 510(k)

of the FD&C Act, upon its own initiative or receipt of a petition from an interested person, if FDA determines that a report under section 510(k) is not necessary to assure the safety and effectiveness of the device. To do so, FDA must publish in the *Federal Register* notice of its intent to exempt the device, or the petition, and provide a 60-calendar day period for public comment. Within 120 days after the issuance of this notice, FDA must publish an order in the *Federal Register* that sets forth its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

The generic device type, powered patient transport is classified under § 890.5150 (21 CFR 890.5150). On March 4, 2013, in response to a petition, FDA created a separate classification for powered patient stairway chair lifts (§ 890.5150(a)), providing a conditional exemption from premarket notification for this device type, product code PCD (78 FR 14015). The classification change retained premarket notification requirements for all other powered patient transport, product code ILK (§ 890.5150(b)).

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the Agency issued on February 19, 1998, entitled “Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff” (available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf>).

As discussed in the guidance document, FDA generally considers the following factors to determine whether a report under section 510(k) is necessary for class II devices: (1) the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and

effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. FDA may also consider that, even when exempting devices, these devices would still be subject to the general limitations on exemptions.

III. Proposed Class II Device Exemptions

FDA has received the following petition requesting an exemption from premarket notification for a class II device: Sam DeMarco, Staff Regulatory Affairs Specialist, on behalf of Stryker Medical, 3800 E. Centre Ave., Portage, MI 49002, for powered patient transport, all other powered patient transport, classified under § 890.5150(b). FDA seeks comment on the petition in accordance with section 510(m)(2) of the FD&C Act.

IV. Paperwork Reduction Act of 1995

While this notice contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this notice. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910-0120.

Dated: June 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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